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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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09/122,427 07/24/98 ZOU

Y UTSC584/G00

EXAMINER

HM12/0317

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PO BOX 4433
HOUSTON TX 77210

AMOUNT PAPER NUMBER

1615
DATE MAILED:

03/17/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2-1-99

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3- month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-29 & 32-51 is/are pending in the application.

Of the above, claim(s) 10-29 & 32-51 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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DETAILED ACTION

1. Applicant's election with traverse of group 1, claims 1-9 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that was set forth by applicants on page 3 of their response. This is not found persuasive because the examiner is required to show the one way distinctiveness between groups and this has been done so in the restriction by the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-29 and 32-51 are withdrawn from consideration.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what is being claimed in claim 1. What does the system have? Water and butanol also? Is it a lyophilized powder? The examiner suggests a revision of the claim.

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Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta (4,950,432).

Mehta discloses preliposomal powders containing a drug and a mixture of phospholipids (note the abstract, columns 6-7, Examples and claims). Phospholipids are surfactants and since the reference teaches a mixture of phospholipids, it meets the requirements of instant claims 2 and 8-9.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 1-2 and 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta (5,811,119).

Mehta discloses preliposomal powders containing retinoic acid and a mixture of phospholipids (note the abstract, columns 6-7 and Examples). Phospholipids are surfactants and since the reference teaches a mixture of phospholipids, it meets the requirements of instant claims 2 and 8-9.

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Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta (4,950,432) or (5,811,119) cited above, further in view of Unger (5,585,112), Isliker (5,089,602), Hsu (5,653,996) individually or in combination.

Mehta does not disclose the use of surfactants such as tweens in the preliposomal preparations.

Unger teaches that non-ionic detergents such as Tweens stabilize the liposome compositions (note col. 25, lines 38-48).

Isliker similarly teaches that Tweens could be used in liposome preparations; the liposome preparations are then lyophilized (Example 11).

Hsu teaches the use of Tweens in liposomal preparations (note col. 5, line 25 et seq.).

In essence, the secondary references all teach the routine practice in the art of the use of Tweens in liposomal preparations. Unger in particular teaches that these are liposomal stabilizers. The use of Tweens in the preparations of Mehta would have been obvious to one of ordinary skill in the art since these are stabilizers and routinely used in the art in liposomal preparations.

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The reference of Alving which teaches that tweens are liposomal stabilizers is cited of interest.

The examiner requests the copies of Foreign references and publications cited on 1449.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 5, 1999